K973513

DEC 22 1997

II. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for modifications to its Visio-Gem® (K833757) and Visio-Gem® Art-System (K905604), to create modified veneer materials that provide improved mechanical properties and aesthetics. The Sinfony® system is indicated for use as a light-curing composite veneer material for:

- full and partial coverage of:
  - fixed crown and bridgework
  - telescopic and conical crowns
  - precision attachments
  - implant superstructures
  - adhesive bridgework
  - laminate veneers
  - individualizing denture teeth
  - individualizing long-term temporary restorations

ESPE is claiming substantial equivalence to its previously cleared Visio-Gem® (K833757) and Visio-Gem® Art-System (K905604). The products have similar intended uses, except that, due to its improved mechanical properties, Sinfony® provides full (not just partial) coverage of crown and bridgework veneers, including occlusal areas. Sinfony® and the Visio-Gem® products also

have similar ingredient composition. Further, both products are intended for use by a dental technician outside the mouth in a commercial dental laboratory or laboratory in a dental office. To support substantial equivalence to the predicate product, the physical and technical characteristics of Sinfony® have been compared to those of Visio-Gem® using tests undertaken pursuant to ISO 10477 and DIN 53456. These characteristics include surface finish, flexural strength, water absorption, solubility, color and translucency, color stability, and surface hardness.

ESPE's 510(k) has been submitted on September 17, 1997, by Dr. Barbara Wagner-Schuh at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Dr. Barbara Wagner-Schuh
Regulatory Affairs
ESPE GmbH & Company KG.
ESPE Platz
D-82229 Seefeld, OBB.

Re: K973513
Trade Name: Sinfony Dentin, Opaque-Dentin, Enamel, Enamel Modifier
Regulatory Class: II
Product Code: EBF
Dated: December 1, 1997
Received: December 4, 1997

Dear Dr. Wagner-Schuh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) # K973513

Device Name: Sinfony® Light-Curing Crown and Bridge Full Coverage Composite Material

Indications for Use:

- Full and partial coverage of:
  - fixed crown and bridgework
  - telescopic and conical crowns
  - precision attachments
  - implant superstructures
  - adhesive bridgework
  - laminate veneers
  - individualizing denture teeth
  - individualizing long-term temporary restorations

Susan Runkel

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973513

Prescription Use X **Or** **Over-the-Counter Use** No